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**Title:** Outcomes of sclerotherapy of the ulcer bed compared to a combination of ablation and injections

Principal Investigator: Jihad Abbas, MD

#### Why is this study being done?

Venous ulcers are the most common cause of ulcerations that affect the lower extremities and are estimated to effect 1% of the American population. They are responsible for more than 80% of lower extremity ulcerations. Treatment for these ulcers can be extensive with poor healing rates. It is imperative for early diagnosis and prompt treatment and to determine any underlying causes at the time of diagnosis to help with healing and prevention.

Management of these ulcers has historically been compression treatment, stripping of the veins, elevation of the effected leg, and exercise. Ablative superficial surgery along with compression is another form of treatment. Ablation is where the problematic vein is sealed off. A catheter is fed up the vein from the ankle or knee level. It is carefully fed, using the aid of ultrasound, to the affected area. An electrical current, or laser energy, is passed through the vein wall causing the vein to contract and seal itself off. This procedure is quicker and less painful compared to the traditional operation of vein stripping. Early ablation of superficial venous reflux in addition to compression has resulted in shorter ulcer healing time and a reduction in the 12-month reoccurrence rate versus compression therapy alone.

Another popular form of treatment is sclerotherapy. Either a foam mixture or a solution is injected into the effected veins causing inflammation and scarring. Over time this leads to destruction of the veins. This treatment is also commonly used with compression therapy. This technique promotes rapid healing usually occurring within 4 to 8 weeks after the initial treatment and long term recurrence rates. This route is much less invasive, quicker, and less painful than the historical procedure of vein stripping.

Although there have been several studies performed on the significance of ablation and sclerotherapy, there is very little data or evidence to support the effectiveness of ablation in addition to sclerotherapy and compression in the treatment of venous ulcers and their reoccurrence. There is also very little data to indicate whether the timing of ablation (at the start of treatment when sclerotherapy is administered, or weeks to months later) has any benefit on healing rates.

You are being asked to participate in a research study to determine the effectiveness of ablation in addition to sclerotherapy and compression in the treatment of venous ulcers and their reoccurrence. We will also be looking at the timing of ablation and whether receiving ablation

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at the start of treatment when sclerotherapy is administered, has any significance over receiving ablation later during treatment.

ProMedica Toledo Hospital will recruit up to 40 patients to be in the study. The goal is to enroll 15 subjects in each arm. You were selected as a possible participant in this study because you have been diagnosed with saphenous vein reflux and have a venous ulcer.

### What will happen if you take part in this study? (Procedures and Duration)

There will be two groups to this study: arm 1 who receives sclerotherapy in addition to ablation at the start of treatment and compression therapy and arm 2 who receives sclerotherapy at the start of treatment along with compression therapy and then ablation 3 months later.

30 opaque envelopes, 15 indicating arm 1 and 15 indicating arm 2, will be prepared by the study coordinator. If you decide to participate in the study, you will select an envelope and treatment will be initiated based upon the arm within the chosen envelope.

After you have selected your envelope and an arm has been identified, you will be asked to fill out a quality of life survey along with the venous clinical severity score (VCSS) questionnaire prior to treatment. You will then have ultrasound-guided sclerosant injected into the affected area. The procedure itself takes approximately 15-30 minutes. If you have selected arm 1, you will then receive ablation at this time. Ablation generally takes approximately 45-60 minutes to complete. If you have selected arm 2, you will undergo ablation at your 3 month visit. Following treatment, you will undergo compression therapy per standard treatment protocol.

You will be seen weekly after receiving treatment to assess healing progress and to ensure patient safety. This is considered standard protocol after receiving this treatment.

Three months after treatment, you will return for a follow up visit where your ulcer size will be measured and your symptoms will be assessed. You will also be asked to fill out another quality of life survey along with the venous clinical severity score (VCSS) questionnaire. If you are in arm 1 this is all that will be required of you during this appointment. If you are in arm 2, you will undergo ablation during this time.

You will continue to be seen weekly to assess healing progress and to ensure safety. Six months after receiving your initial treatment, you will return for a follow up visit where your ulcer size will be measured and your symptoms will be assessed. You will also be asked to fill out another quality of life survey along with the venous clinical severity score (VCSS) questionnaire. Your participation in the study will be complete after your 6 month appointment. You will continue to see your physician for treatment, if needed, after your participation has concluded.

In addition, patient demographics and medical history that are obtained from the medical staff will be used in the study evaluation. Variables that will be collected will include: age, gender, race, treatment, treatment completed, quality of life (QOL) questionnaires, venous clinical severity score (VCSS) questionnaires, ulcer size, BMI, tobacco use, alcohol use hemoglobin Health System

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A1C (most current value if available), NSAIDS, steroids, chemotherapy, radiation, comorbidities, and family history.

### What side effects or risks could result from being in this study?

During the sclerosant injections, some people experience minor stinging or cramps when the needle is inserted into the vein. The risks associated with the injection include, but are not limited to, bruising, raised red areas, small skin sores, darkened skin in the form of lines or spots, and multiple tiny red blood vessels. These side effects usually go away within a few days to several weeks. Other more serious side effects include, but are not limited to, inflammation, blood clot, air bubbles and allergic reaction. Please be sure to call your doctor right away if you think you are experiencing any of these more serious side effects.

For an ablation, if local anesthetic is used, you may experience slight pinpricks as the anesthetic is injected. You may also feel slight pressure when the catheter is inserted. The risks associated with an ablation include but are not limited to, infection, blood vessel damage, swelling, pain over the treated vein, nerve damage, and bruising or bleeding at the puncture site.

There are also risks associated with privacy and possible loss of confidentiality. The research team will make all reasonable efforts to protect your personal information and will maintain all medical records in accordance with federal and state laws.

# What are the benefits to participating and will you be paid to participate?

You may or may not recieve any personal benefits from being in this study. It is anticipated that other people may benefit from the results of this study in the future. We cannot and do not guarantee or promise you will recieve any benefits from this study. You will not be provided any compensation to participate in this study.

## What other choices do you have if you do not take part in this study?

If you choose not to participate in this study, you will be treated for venous ulcers according to the standard of care at ProMedica Toledo Hospital. Your decision to not participate will not affect your relationship with your physician(s) or any other member of the medical team, nor will it affect your relationship with ProMedica Toledo Hospital, or ProMedica Health System.

### Will your medical information be kept private?

Your medical records will be maintained in accordance with federal and state laws. Efforts will be made to keep your personal information confidential. The research investigator(s) cannot guarantee absolute confidentiality. Private identifiable information about you may be used or disclosed for the purpose of conducting this research project as described earlier in the consent form. The information that may be used or disclosed includes the following: physician/clinic records, hospital records, and questionnaires. If the results of the study are reported in medical journals or presented, you will not be identified and all data will be presented in aggregate format.

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You have the right to access your medical records. You may request that your research medical record be released to your personal physician. Organizations that may inspect and/or copy your research medical records for quality assurance and data analysis include: ProMedica Institutional Review Board. This information may be further disclosed if the recipient(s) described on this form are not required by law to protect the privacy of the information

The use and disclosure of your protected health information will conclude at the end of this study; If after you have entered this study and you wish to withdraw from participation, you have the right to change your mind about allowing the investigator to have access to this health information, although the investigator may use information already collected to maintain the completeness of the study.

If you decide to revoke permission to use your personal information, please contact Jobst Vascular Institute:

Jobst Vascular Institute 2106 Hughes Drive, CJT#400 Toledo, Ohio 43606 419-291-2088

If you have any further questions about your privacy, you may contact the *confidential ProMedica Hotline at* (419) 824-1815 or (800) 807-2693.

### What are the costs of taking part in this study?

You will not incur any additional costs by participating in this study. All treatments and appointments are considered standard of care and will be billed to your insurance.

### What happens if you are injured because you took part in this study?

It is highly unlikely that you will get hurt or sick as a result of being in this study. In the event you believe your participation has caused harm, you should seek treatment at the nearest medical facility. The research team will not pay the costs of your medical treatment for any injury or illness that is a result of participation in the research study or a result of the procedures performed according to the study plan. If you require treatment, you should notify **Dr. Jihad Abbas** as soon as possible at **419-291-2088**. Financial compensation is not available from ProMedica Health System, Inc. or ProMedica Toledo Hospital. By signing this form, you are not giving up any of your legal rights as a research subject.

## Are any research team members being paid for conducting this study?

No members of the research team are being paid to conduct this study.

### What are your rights if you take part in this study?

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect your future relations with any ProMedica institution, its personnel, and associated hospitals or facilities. You have the right not to participate in this study, and refusing to participate will not affect the present or future medical care you receive and will not realized Health System

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any penalty or loss of benefits to which you are otherwise entitled. If you withdraw from the study early, the research team may continue to collect follow-up information on your health status to be used as part of the study if you agree.

### What other things should you know about participating in this study?

If new research or findings develop during the time in which you are participating in this research that may influence your willingness to continue, that information will be provided to you.

## Who can answer your questions about the study?

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think this over. If you have any questions regarding your rights as a research patient, you may contact the Chairperson of the ProMedica Institutional Review Board at 419-291-5362, during office hours Monday through Friday, 8 a.m. to 4:30 p.m.



Subject Name:_	
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Signatures:
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You are making a decision whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to participate.

Printed Name of Subject	
Signature of Subject	Date/Time
(If Applicable) Printed Name of Legally Authorized Representative	Relationship to Subject
Signature of Legally Authorized Representative	Date/Time
Printed Name of Person Obtaining Consent	
Signature of Person Obtaining Consent	Date/Time

#### YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries, please feel free to contact the ProMedica Institutional Review Board at 419-291-5362.

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